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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,382	03/14/2007	Kenneth Powell	NV2-020US	8889
959 7590 04/28/2009 LAHIVE & COCKFIELD, LLP FLOOR 30, SUITE 3000 ONE POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER PHONAK, SARAH				
ART UNIT		PAPER NUMBER		
4121				
MAIL DATE		DELIVERY MODE		
04/28/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/593,382

**Applicant(s)**

POWELL ET AL.

**Examiner**

SARAH PIHONAK

**Art Unit**

4121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

This application is a 371 (national stage application) of PCT/GB05/01029, filed on 3/18/05, and claims foreign priority to Application No. 0406279.0, filed on Great Britain on 3/19/04.

#### ***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) component (a) of instant claim 1, which is a compound of general formula (I) and (II);

b) component (b) of instant claim 1, which is a compound of general formula (V) and (Va).

Claim 1 is generic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

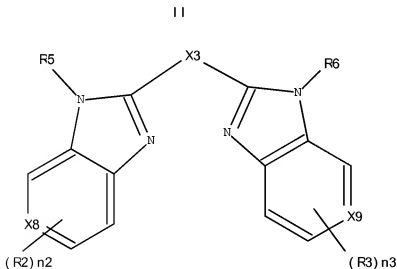
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

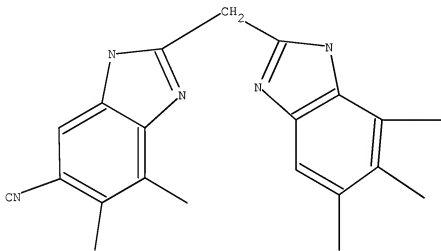
a) each chemical species is a distinct chemical which lacks a special technical feature in view of Evans et. al., US 4,820,834 patent, and Church et. al., WO 98/45275.

The US '834 patent discloses a benzodiazepine compound of general formula (V) and (Va) (column 85, Table 13, No. 688). The WO '275 publication also discloses compounds of general formula (II), which are also described by general formula (I) in the instant application (pp. 86-87, claims 1-2). For example, the WO '275 publication discloses compounds of the general formula (II) below:



Where X<sub>8</sub>=-CH(R<sub>1</sub>)n<sub>1</sub>, etc., X<sub>9</sub>=-CH(R<sub>4</sub>)-; X<sub>3</sub>=-CR<sub>7</sub>R<sub>8</sub>; R<sub>2</sub>=C<sub>1</sub>-6 alkyl, etc., R<sub>3</sub>=C<sub>1</sub>-6 alkyl; R<sub>5</sub>=H, etc., R<sub>6</sub>=H, etc., R<sub>1</sub>=cyano, etc., R<sub>4</sub>=H, etc., R<sub>7</sub>=H, etc., R<sub>8</sub>=H, etc.

(pp. 86-87, claims 1-2). Compounds of the general formula II above are also included in compounds of general formula (I) of the instant application.



The compound shown directly above is a species of general formula II, as disclosed by the WO '275 publication (pp. 86-87, claims 1-2). Additionally, this compound is also a species of general formula (I), as cited in the instant application. Therefore, the US '834 patent and the WO '275 publication disclose species of compounds of formula (V) and (I). As such, the species are anticipated by the prior art, and do not present a special technical feature over the prior art. Therefore, unity of invention regarding the species is lacking.

### ***Election of Species***

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

a) *Core compound with multiple R, X, A, Y, and n groups*: a benzodiazepine derivative of general formula (V) and (Va) as recited by claims 1-38;

b) *Core compound with multiple R, X, Y, Z, Q, A, B, L, and n groups*: an inhibitor of the RSV fusion protein of general formula (I) and (II) as recited by claims 1-38.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1-38, Applicant is required to define each of  $R^1$ - $R^n$ ,  $X^1$ - $X^n$ ,  $A^1$ - $A^n$ , and Y groups as required for the benzodiazepine species component (b) of general formula (V) and (Va) (a species for example is methyl, NOT alkyl). As to claims 1-38, Applicant is required to define each  $R^1$ - $R^n$ , X, Y, n, Z, Q,  $A^1$ - $A^n$ ,  $B^1$ - $B^n$ , and L groups as required for the inhibitor of the RSV fusion protein component (a).

Upon Applicant's election of species, the result must provide a single chemical species and a single condition or disease to be treated or improved. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: the species of general formula (V), (Va), and (I) are anticipated by the US '834 patent (column 85, Table 13, No. 688) and the WO '275 publication (pp. 86-87, claims 1-2).

5. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S.P.

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4121